Application No. 10/584,445

Submission dated December 3, 2009

## AMENDMENTS TO THE CLAIMS

(Previously Presented) Vinflunine pharmaceutical composition, wherein it is in the form
of a stable and sterile aqueous solution of a water-soluble vinflunine salt at a pH of
between 3 and 4 and wherein the composition does not contain any sugar, sugar-based
polyol or other preservatives.

- (Previously Presented) Composition according to Claim 1, wherein the vinflumine salt is vinflumine ditartrate.
- (Previously Presented) Composition according to Claim 2, wherein the composition consists of vinflunine ditartrate and water for an injectable preparation.
- (Previously Presented) Composition according to Claim 1, wherein it comprises a pH buffer system in order to maintain the pH between 3 and 4.
- (Previously Presented) Composition according to Claim 4, wherein the molarity of the pH buffer system is between 0.002 M and 0.2 M.
- (Previously Presented) Composition according to Claim 4, wherein the pH buffer system
  consists of an acetic acid/sodium acetate buffer or a citric acid/sodium citrate buffer.
- (Previously Presented) Composition according to Claim 2, wherein the composition
  contains vinflunine ditartrate with a base vinflunine concentration of between 1 and
  50 mg/ml.
- (Previously Presented) Composition according to Claim 2, wherein it corresponds to one
  of the following formulations: 68.35 mg of vinflunine ditartrate qs 2 ml in water or
  136.70 mg of vinflunine ditartrate qs 4 ml of water or 341.75 mg of vinflunine ditartrate

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qs 10 ml of water, the vinflunine ditartrate corresponding, respectively, to 50 mg of base vinflunine, 100 mg of base vinflunine and 250 mg of base vinflunine.

- (Previously Presented) Composition according to claim 1, wherein it remains stable for at least 36 months at 5°C±3°C.
- 10. (Withdrawn) Method for treating cancer comprising the parenteral administration of an effective amount of a composition according to Claim 1 to a patient in need thereof.
- 11. (Cancelled).
- (Withdrawn) Process for preparing a composition according to Claim 1, comprising the following successive steps:
  - (a) dissolution of the vinflunine salt in water for injectable preparations,
  - (b) optional addition of a pH buffer,
  - (c) sterilization by filtration of the bulk solution,
  - (d) aseptic distribution, under a nitrogen atmosphere, of the sterile composition obtained in step (c) in the container, advantageously chosen from glass phials, glass bottles and prefilled syringes.
- (Previously Presented) Packaging container containing the composition according to Claim 1.
- (Previously Presented) Composition according to claim 7, wherein it contains vinflunine ditartrate with a base vinflunine concentration of between 25 and 30 mg/ml.
- (Previously Presented) Composition according to claim 14, wherein it contains vinflunine ditartrate with a base vinflunine concentration of 25 mg/ml.

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 (Withdrawn) Method for treating cancer according to claim 10, wherein the parenteral administration is via intravenous perfusion.

17. (New) A pharmaceutical composition consisting essentially of an effective amount of vinflunine ditartrate in the form of a stable and sterile aqueous solution at a pH between 3 and 4.

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